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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,614	11/10/2003	James F. Hainfeld	16049Z	4692

23389 7590 05/01/2008

SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
HOPKINS, CHRISTINE D	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,614	HAINFELD ET AL.	
	Examiner	Art Unit	
	CHRISTINE D. HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,25,69 and 71-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-22,25,88 and 89* is/are allowed.

6)☒ Claim(s) *69,71-81 and 83-87* is/are rejected.

7)☒ Claim(s) *82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 17 January 2008. Claims 1-22, 25, 69 and 71-89 are now pending. The Examiner acknowledges the cancellation of claim 70.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 69, 71-81 and 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440) in view of Patel (U.S. Pub. No. 2005/0180917). Since Applicant fails to disclose adequate support for the claim limitations of claim 23 in Serial No. 09/363204 filed on July 29, 1999, Patel is applied as prior art under 35 U.S.C. 103(a). Esenaliev discloses the use of nanoparticles with various forms of radiation for enhancing drug delivery in tumors. Regarding claims 69, 71-72 and 87, Esenaliev teaches a method of enhancing the effects of radiation via the administration of an anti-cancer drug to a tumor, injection of nanoparticles intravenously, and subsequent irradiation of the tumor (col. 5, lines 41-46). The tumor being irradiated may be that of brain, lung or breast tissue (col. 5, lines 50-53), in accordance with claims 73-75. Referring to claims 76-78, such particles injected

intravenously may comprise gold (col. 10, lines 14-18). Regarding claims 79-81, and 83-86, since the nanoparticles have a surface layer of material such as an antibody coating, the metal portion of the nanoparticle is being interpreted as the "metal core." Thus, Esenaliev discloses a metal core in the range of 0.1 nm to about 7000 nm (col. 2, lines 20-28). However, Esenaliev fails to disclose a particular concentration of metal to be achieved within the tissue treated. Patel teaches the treatment of cancer at the site of, and area adjacent to, the tumor via irradiation of the diseased tissue. Regarding claim 69, Patel teaches nanoparticles comprising a metal, such as gold, at a concentration of about 0.1% by weight [0042]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a metal concentration as suggested by Patel, to the composition of a nanoparticle as taught by Esenaliev, such that the susceptibility of a tumor to radiation treatment is enhanced.

Allowable Subject Matter

4. Claims 1-22, 25 and 88-89 are allowable over the prior art of record. Regarding claims 1-22 and 25, the prior art of record does not teach or fairly suggest a method of enhancing the effects of radiation in an animal comprising administering an amount of metal nanoparticles to said animal and subsequently irradiating the animal with radiation wherein the radiation is in a form selected from the group consisting of x-rays, microbeam arrays of x-rays, radioisotopes, electrons, protons, ion means, and neutrons wherein the metal nanoparticles are administered in an amount to achieve a concentration in the animal of at least about 0.1% metal by weight.

Regarding claim 88, the prior art of record does not teach or fairly suggest a method of enhancing the effects of radiation in an animal comprising administering an amount of metal nanoparticles to said animal and subsequently irradiating the animal with radiation wherein said nanoparticles comprise a surface layer material comprising thoioglucose. Regarding claim 89, the prior art of record does not teach or fairly suggest a method of enhancing the effects of radiation in an animal comprising administering an amount of metal nanoparticles to said animal and subsequently irradiating the animal with radiation wherein said nanoparticles are polyanions of metals complexed with quaternary ammonium salts.

5. Claim 82 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 82, the prior art of record does not teach or fairly suggest a method of enhancing the effects of radiation in an animal comprising administering an amount of metal nanoparticles to said animal and subsequently irradiating the animal with radiation wherein the metal nanoparticles are administered in an amount to achieve a concentration in the animal of at least about 0.1% metal by weight wherein the nanoparticles comprise a surface layer material comprising a sulfur, phosporus or amine group.

Response to Arguments

6. Applicant's arguments filed 17 January 2008 with respect to the rejection of claims 69, 71-87 and 83-86 under 35 U.S.C. 103(a) citing Esenaliev ('440) in view of Patel (U.S. Pub. No. 2005/0180917) have been fully considered and are not persuasive. Applicant contends that a previous rejection based on the combination of Esenaliev and Patel had been overcome based on distinguishing the references. However, this argument is not persuasive. The rejection to which Applicant refers incorporated a further limitation which in fact overcame that particular rejection, and was thus indicated as allowable subject matter. Applicant further contends that the invention to Patel refers to metal concentrations present in the nanoparticle itself, and not the percentage of nanoparticles in the target tissue as recited in the present claims. However, this argument is not persuasive. The language of the claim does not limit the concentration of the nanoparticle to the tissue itself. The claim is interpreted in the most reasonably broad fashion, therefore it is construed to also mean the concentration of the metal in the nanoparticle, which also resides in the tissue. In view of the foregoing, the rejection of claims 69, 71-87 and 83-86 under 35 U.S.C. 103(a) citing Esenaliev ('440) in view of Patel (U.S. Pub. No. 2005/0180917) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735